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News Releases

DexCom Achieves Clinical And Regulatory Milestones

Seven-Day Study Completed with Short-Term Sensor (STS) 100-Day Meeting with FDA for STS PMA Completed

San Diego, CA --- July 25, 2005 --- DexCom Inc. (NASDAQ:DXCM) today announced two clinical and regulatory milestones.

DexCom announced the completion of an 86-patient, 21-day trial in the United States with its Short-Term Continuous Glucose Monitoring System (STS) that evaluated performance over three consecutive seven-day periods. Patients inserted the STS sensors themselves, wore them in their daily activities at home and work, and were allowed to view and utilize the real-time continuous glucose data from the STS System. The study demonstrated that the STS System functioned reliably over a seven-day period without a decline in sensor performance or any signs of infection at the insertion site. Although the specific regulatory path and timing are not yet determined, the Company intends to seek FDA approval for a seven-day STS sensor, in addition to the three-day STS system currently under review. DexCom expects the data from this study to be presented or published by the study investigators in the future. "Since we filed our PMA for the three-day STS Continuous Glucose Monitoring System in March, we have continued to further develop the product platform and underlying technology," said Andy Rasdal, President and CEO of DexCom. "We have been able to leverage technology developed as part of our long-term implantable sensor program to the STS product platform and demonstrated with this latest study that our STS product functioned reliably for a seven-day period. While we continue to believe that our three-day STS system currently under review by the FDA could represent a significant breakthrough in the management of diabetes, we also believe a sensor that needs to be replaced only once per week would offer a new level of convenience in disease management to people with diabetes."

DexCom also announced that the Company had its 100-day meeting with the FDA in regard to its PMA application for the STS Continuous Glucose Monitoring System currently under review by the FDA. The 100-day meeting is a regulatory meeting where the FDA reviews the status of the PMA application with the Company and typically makes requests for additional information. At this 100-

day meeting, the FDA made requests of DexCom for additional analysis and information to support its STS PMA filing. In accordance with normal FDA procedures, the FDA will be outlining these requests in writing in what is called a major deficiency letter. DexCom considers all of the requests made at the meeting to be readily answerable and expects to provide the requested information in an expeditious manner. The FDA did not make any request for DexCom to conduct additional clinical studies. "Since May, when our STS PMA was accepted as filed and granted expedited review status, we have had an interactive and timely review with the FDA," said Andy Rasdal, President and CEO. We believe the 100-day meeting was very productive and continued to further the common understanding between DexCom and the FDA regarding our STS PMA application and continuous glucose monitoring."

About DexCom Inc.

DexCom Inc., headquartered in San Diego, California, is developing continuous glucose monitoring systems for people with diabetes.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward looking statements concerning our beliefs concerning our product development efforts and our expectations regarding FDA reviews that are subject to significant risks and uncertainties. Actual results could differ materially. The regulatory approval process for our continuous glucose monitoring systems involves, among other things, successfully completing clinical trials and obtaining a premarket approval, or PMA, from the FDA. The PMA process requires us to prove the safety and efficacy of our systems to the FDA's satisfaction. This process can be expensive and uncertain, and there is no guarantee that the PMA application we recently submitted for our three-day sensor, or any future submissions, will be approved by the FDA in any specific timeframe or at all. In addition, clinical testing of our products and eventual commercialization of our products are subject to all of the risks and uncertainties set forth in our registration statement filed with the Securities and Exchange Commission.

FOR MORE INFORMATION:

Steve Kemper
Chief Financial Officer
(858) 200-0200

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News Releases

DexCom Files Response To Support STS PMA Application

San Diego, CA --- September 12, 2005 --- DexCom, Inc. (NASDAQ:DXCM) today announced it has submitted the information requested by the FDA at the 100-day meeting for DexCom's PMA application for its Short-Term Continuous Glucose Monitoring System. DexCom filed its PMA for the STS Continuous Glucose Monitoring System in March, received expedited review status in May, had its 100-day meeting with the FDA in late July, and received the information requests arising from the 100-day meeting in a letter in late August. The Company believes the response just filed comprehensively addresses these FDA requests. Providing this response does not prevent the FDA from making further information requests nor does it guarantee approval of the STS Continuous Glucose Monitoring System.

About DexCom, Inc.

DexCom, Inc., headquartered in San Diego, California, is developing continuous glucose monitoring systems for people with diabetes.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward looking statements concerning our beliefs concerning our product development efforts and our expectations regarding FDA reviews that are subject to significant risks and uncertainties. Actual results could differ materially. The regulatory approval process for our continuous glucose monitoring systems involves, among other things, successfully completing clinical trials and obtaining a premarket approval, or PMA, from the FDA. The PMA process requires us to prove the safety and efficacy of our systems to the FDA's satisfaction. This process can be expensive and uncertain, and there is no guarantee that the PMA application we recently submitted for our three-day sensor, or any future submissions, will be approved by the FDA in any specific timeframe or at all. In addition, clinical testing of our products and eventual commercialization of our products are subject to all of the risks and uncertainties set forth in our registration statement filed with the Securities and Exchange Commission.

FOR MORE INFORMATION:

Steve Kemper
Chief Financial Officer
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EXHIBIT C

2003 Judicial Business

Annual Report of the Director
Leonidas Ralph Mecham

This report was produced by the Statistics Division
Office of Judges Programs
Administrative Office of the U.S. Courts
Thurgood Marshall Federal Judiciary Building
Washington, DC 20544

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Table C-10.
U.S. District Courts—Median Time Intervals from Filing to Trial of Civil Cases in Which Trials Were Completed, by District, During the 12-Month Period Ending September 30, 2003

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Intervals in Months*	Number of Trials	Median Time Intervals in Months*	Number of Trials	Median Time Intervals in Months*
TOTAL	**3,930**	**22.5**	**1,361**	**21.5**	**2,569**	**23.2**
DC	**46**	**25.0**	**25**	**24.0**	**21**	**29.0**
1ST	**214**	**22.2**	**71**	**22.4**	**143**	**23.2**
ME	16	14.7	4	-	12	14.4
MA	94	28.5	34	23.0	60	29.0
NH	11	17.0	3	-	8	-
RI	26	22.5	14	24.0	12	20.0
PR	67	21.5	16	6.4	51	21.5
2ND	**432**	**29.0**	**158**	**29.0**	**274**	**29.0**
CT	65	30.0	17	32.0	48	29.0
NY,N	38	32.0	8	-	30	32.0
NY,E	128	35.3	45	34.0	83	35.0
NY,S	180	22.6	82	21.7	98	23.0
NY,W	11	48.0	1	-	10	45.0
VT	10	22.0	5	-	5	-
3RD	**371**	**25.6**	**101**	**22.5**	**270**	**25.2**
DE	37	24.0	9	-	28	21.5
NJ	71	33.8	19	31.0	52	34.5
PA,E	126	19.0	36	14.0	90	19.0
PA,M	69	23.0	10	21.0	59	23.3
PA,W	59	34.2	20	29.0	39	34.6
VI	9	-	7	-	2	-
4TH	**254**	**17.7**	**95**	**15.3**	**159**	**18.8**
MD	41	23.0	16	25.0	25	21.7
NC,E	9	-	3	-	6	-
NC,M	12	21.5	4	-	8	-
NC,W	7	-	-	-	7	-
SC	71	22.5	25	23.0	46	21.4
VA,E	67	8.0	26	8.2	41	8.5
VA,W	31	15.5	15	13.0	16	15.0
WV,N	6	-	3	-	3	-
WV,S	10	15.0	3	-	7	-

Table C-10. (September 30, 2003—Continued)

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Intervals in Months*	Number of Trials	Median Time Intervals in Months*	Number of Trials	Median Time Intervals in Months*
5TH	**531**	**19.9**	**218**	**17.5**	**313**	**19.6**
LA,E	103	17.4	54	20.0	49	15.5
LA,M	14	26.0	5	-	9	-
LA,W	38	19.0	24	19.0	14	18.0
MS,N	30	24.0	6	-	24	24.5
MS,S	38	19.4	14	16.0	24	21.5
TX,N	82	18.6	26	17.2	56	19.0
TX,E	76	17.0	25	16.0	51	18.8
TX,S	99	20.8	48	15.3	51	23.0
TX,W	51	16.5	16	16.7	35	17.0
6TH	**327**	**22.0**	**94**	**21.3**	**233**	**22.1**
KY,E	28	21.0	4	-	24	21.0
KY,W	20	27.5	1	-	19	27.5
MI,E	47	23.8	16	23.0	31	23.5
MI,W	23	22.0	7	-	16	20.0
OH,N	47	22.0	16	19.0	31	25.5
OH,S	36	25.7	12	20.0	24	29.7
TN,E	28	16.3	9	-	19	17.5
TN,M	58	27.0	19	21.0	39	27.8
TN,W	40	18.0	10	20.0	30	18.8
7TH	**243**	**23.7**	**91**	**20.0**	**152**	**24.2**
IL,N	106	26.0	41	26.7	65	27.0
IL,C	36	23.5	10	21.0	26	23.5
IL,S	28	23.0	11	17.0	17	26.5
IN,N	18	26.0	8	-	10	26.0
IN,S	24	24.0	12	15.0	12	26.0
WI,E	12	18.0	2	-	10	17.0
WI,W	19	8.4	7	-	12	8.7
8TH	**324**	**20.7**	**106**	**17.3**	**218**	**21.2**
AR,E	78	22.5	37	16.0	41	23.8
AR,W	34	14.0	7	-	27	14.0
IA,N	12	20.0	4	-	8	-
IA,S	7	-	1	-	6	-
MN	40	24.5	11	22.0	29	25.0
MO,E	43	19.0	13	18.0	30	20.0
MO,W	45	21.0	6	-	39	20.0
NE	38	15.0	19	16.5	19	15.0
ND	8	-	1	-	7	-
SD	19	19.0	7	-	12	20.0

Table C-10. (September 30, 2003—Continued)

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Intervals in Months*	Number of Trials	Median Time Intervals in Months*	Number of Trials	Median Time Intervals in Months*
9TH	**508**	**26.8**	**219**	**24.3**	**289**	**28.7**
AK	12	31.0	7	-	5	-
AZ	50	34.0	21	32.5	29	37.0
CA,N	72	30.3	28	24.0	44	31.0
CA,E	32	34.0	7	-	25	38.0
CA,C	182	21.2	81	18.7	101	23.2
CA,S	26	23.5	12	29.0	14	22.7
HI	6	-	2	-	4	-
ID	13	36.0	5	-	8	-
MT	12	24.0	8	-	4	-
NV	36	32.0	19	28.0	17	40.0
OR	25	21.5	9	-	16	22.0
WA,E	6	-	3	-	3	-
WA,W	32	16.7	14	16.0	18	17.0
GUAM	3	-	3	-	-	-
NMI	1	-	-	-	1	-
10TH	**271**	**21.7**	**65**	**22.4**	**206**	**20.6**
CO	66	26.0	21	25.0	45	27.0
KS	37	21.0	10	22.0	27	20.0
NM	28	21.7	4	-	24	20.0
OK,N	31	18.0	11	18.0	20	18.0
OK,E	5	-	1	-	4	-
OK,W	55	16.8	4	-	51	16.2
UT	24	27.0	9	-	15	25.0
WY	25	13.0	5	-	20	11.0
11TH	**409**	**20.7**	**118**	**17.2**	**291**	**21.0**
AL,N	35	18.4	4	-	31	17.0
AL,M	19	18.0	5	-	14	18.0
AL,S	11	17.0	3	-	8	-
FL,N	18	20.0	10	23.0	8	-
FL,M	86	20.2	23	19.0	63	20.2
FL,S	133	18.3	53	15.5	80	22.5
GA,N	59	25.5	13	28.0	46	24.0
GA,M	28	26.0	3	-	25	28.0
GA,S	20	30.0	4	-	16	32.0

NOTE: INCLUDES TRIALS CONDUCTED BY DISTRICT AND APPELLATE JUDGES ONLY. ALL TRIALS CONDUCTED BY MAGISTRATE JUDGES ARE EXCLUDED. EXCLUDES THE FOLLOWING TRIALS: LAND CONDEMNATION; FORFEITURES AND PENALTY CASES; PRISONER PETITIONS (HABEAS CORPUS, MOTIONS TO VACATE SENTENCE UNDER 28 U.S.C. 2255, HEARINGS ON EVIDENTIARY MATTERS); BANKRUPTCY PETITIONS; AND THREE-JUDGE COURT CASES. FOR CIVIL CASES RESULTING IN A COMPLETED TRIAL, THE MEDIAN TIME IS BASED ON THE ORIGINAL FILING DATE AND THE DATE THE TRIAL WAS COMPLETED. FOR REOPENED CIVIL CASES RESULTING IN A SECOND COMPLETED TRIAL, THE MEDIAN TIME REMAINS BASED ON THE ORIGINAL FILING DATE AND THE DATE THE TRIAL WAS COMPLETED.

* TIME INTERVALS COMPUTED ONLY FOR 10 OR MORE TRIALS.

EXHIBIT D

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 357326 (S.D.Fla.), 18 Fla. L. Weekly Fed. D 198
(Cite as: 2005 WL 357326 (S.D.Fla.))

C

Motions, Pleadings and Filings

United States District Court,
S.D. Florida.
ALPHAMED PHARMACEUTICALS CORP.,
Plaintiff,
v.
ARRIVA PHARMACEUTICALS, INC. f/k/a
Alphaone Pharmaceuticals, Inc., et al.,
Defendants.
No. 03-20078-CIV.

Filed Jan. 14, 2003.
Jan. 5, 2005.

James Edward McDonald, Lida Rodriguez-Taseff, Michelle Gervais-Kullman, Duane Morris, Miami, FL, for Alphamed Pharmaceuticals Corp., plaintiff.

Eric Saida, Baker & McKenzie, Miami, FL, James Edward McDonald, Lida Rodriguez-Taseff, (See above), for John, Jarrett, Noreen and Darren Lezdey, plaintiff.

Steven Wayne Marcus, Ruden McClosky Smith Schuster & Russell, Fort Lauderdale, FL, Jay Barry Green, Green Ackeerman & Frost, Boca, FL, Jonathan Goodman, Julie Elizabeth Nevins, Akerman Senterfitt, Miami, FL, Paul Joseph Riley, IV, Jason A. Crotty, Morrison & Foerster, San Francisco, CA, Dale Lyn Friedman, Conroy Simberg Ganon Krevans & Abel, Hollywood, FL, David Reich Chase, Penthouse, David R. Chase, Hollywood, FL, Frank Herrera, Miami, FL, for Arriva Pharmaceuticals, Inc., a California Corporation fka AlphaOne Pharmaceuticals, Inc., defendant.

Jay Barry Green, (See above), Jeffrey David Feldman, Steven Eric Eisenberg, Feldman Gale, Miami, FL, for Spinelli Corporation, an Arizona corporation, defendant.

Jay Barry Green, (See above), Ilana K. Green, Green Ackeerman & Frost, Boca, FL, Ilana K. Green, Akerman Senterfitt, Miami, FL, for CTG & Associates LLC, a Georgia limited liability company and, defendant.

Jay Barry Green, Ilana K. Green, (See above), for Norman Transeth, an individual, defendant.

Eric Saida, Baker & McKenzie, Miami, FL, James Edward McDonald, Duane Morris, Miami, FL, Douglas J. Rovens, Zelle Hoffmann Voebel Mason & Gette, Los Angeles, CA, for John Lezdey, defendant.

ORDER ON MOTION TO DISMISS

ALTONAGA, J.

*1 THIS CAUSE came before the Court upon Defendant, Arriva Pharmaceuticals, Inc.'s ("Arriva") Motion to Dismiss the Second Amended Complaint (D.E.289), filed on September 10, 2004. The Court has reviewed the written submissions of the parties, the relevant portions of the record, and applicable law, and heard oral argument on December 17, 2004.

I. *FACTUAL AND PROCEDURAL BACKGROUND*

The following allegations are contained in the Third Amended Complaint ("TAC"). This case arises out of competition in the pharmaceutical industry between Plaintiff, AlphaMed Pharmaceuticals Corp. ("AlphaMed") and Arriva. AlphaMed is a biotechnology engineering and manufacturing firm, which is involved in the development and production of Alpha 1-Antitrypsin ("AAT"), a therapeutic protein produced naturally by the liver, which is released into the blood stream to protect tissue cells from damage caused by enzymes produced as the result of infection or inflammation within the body (¶¶ 12, 18). [FN1] AAT is extremely useful for treating a wide range of human and veterinary indications, and pharmaceutical companies all over the world have undertaken significant research efforts to develop a method for the mass production of bio-synthetic AAT (¶ 12). Currently, the Federal Food and Drug Administration (the "FDA") has approved only one method for the mass production of AAT (¶ 13). This method derives AAT from blood plasma (¶ 13). Bayer Pharmaceuticals Corporation manufactures the only drug on the market that uses blood derived AAT, and that drug (Prolastin) has been approved by the FDA only for the treatment of hereditary emphysema (¶ 14).

FN1. All paragraph references are to the TAC.

On or about October 26, 2001, AlphaMed filed a patent application for a patent in the United States and abroad to cover a method for the mass production of glycosylated [FN2] AAT, derived from *Pichia pastoris* yeast cells (¶ 21). The pending patent application has been assigned U.S. Serial No. 09/981,073 (¶ 21). More important to this case, by

assignment dated April 10, 2001 from J & D Sciences, Inc ., AlphaMed is the owner of U.S. Patent No. 6,174,859 (the " '859 patent"), which covers the treatment of eye and ear infections (including otitis media and otitis externa in humans or animals) through the application of AAT and/or secretory leucocyte protease inhibitor ("SLPI") (¶ 23). [FN3] No other entity is permitted to make, use, sell, offer to sell, or import into the United States the technology claimed in the '859 patent without the permission and/or express authorization of AlphaMed (¶ 24).

> FN2. The term "glycosylated" refers to the presence of mannose or sugar groups in the AAT molecules. This characteristic is significant because the presence of mannose or sugar groups in the AAT molecules decreases the likelihood that the foreign AAT will be rejected by the human body.

> FN3. Arriva claims the '859 was fraudulently transferred to AlphaMed, but for purposes of this Motion, the Court does not consider that claim.

Arriva is also a biopharmaceutical company, and its main corporate mission at the time of its creation was to develop a genetically engineered version of the drug Prolastin for use in pulmonary and topical applications (¶ 25). Arriva currently claims to focus on the development and commercialization of recombinant protease inhibitors for treatment of a wide range of human diseases, including eye and ear infections (¶ 26). Arriva has raised millions of dollars for research and clinical trials designed to put it in a position to exploit the worldwide market for AAT (¶ 27). AlphaMed claims that Arriva has engaged in corporate espionage against AlphaMed in an attempt to develop the intellectual property necessary for exploitation of the market for AAT, including obtaining AlphaMed's trade secrets (¶¶ 28-29; 41-53; 110-121). [FN4]

> FN4. The allegations of corporate espionage are the most contentious in this case and formed the basis of two RICO counts that were included in the Second Amended Complaint but are not in the TAC. Most of these allegations are not directly relevant to the present Motion.

***2** In September 1999, Arriva sought to have AlphaMed investigated by the FBI, and used a private investigation firm, Defendant, Spinelli Corporation ("Spinelli"), to try to convince the FBI to seek criminal charges against AlphaMed and its principals (¶ 29). Among other statements, Arriva and Spinelli told the FBI that Arriva was the owner of the specific DNA genetic source code for manufacturing AAT (¶ 30). The FBI ultimately did not file criminal charges against AlphaMed, but Arriva used the investigation to cause substantial financial damage to AlphaMed (¶ 31). Among that damage was a business relationship with Robert Williams ("Williams"), AlphaMed's chief investor (¶ 124). Williams had invested more than $1 million in AlphaMed and was preparing to invest another $1 million before Arriva allegedly disrupted the financial relationship (¶ 124). Just as AlphaMed and Williams were in the process of finalizing an agreement for additional financing in late March 2001, an agent of Arriva's called Williams and stated that he was investigating a complaint made by "members of the Wachter family [Dr. Alan Wachter was the medical director of Arriva] against the Lezdey family [the principals of AlphaMed]" (¶ 126). Because this agent continued to call him and purport to be an FBI agent, Williams decided not to make any more investments in AlphaMed (¶ 128).

In 2001, Arriva claimed it had developed technology for the large-scale production of stable, non-animal sourced recombinant proteins through the use of *Saccharomyces cerevisiae,* another type of genetically engineered yeast cell (¶ 32). This claim was false because ZymoGenetics, Inc. had already received a patent for the production of AAT using *Saccharomyces cerevisiae* yeast cells (U.S. Patent No. 5,218,091) (the " '091 patent") (¶ 33). Arriva obtained a license from ZymoGenetics, Inc. ("ZymoGenetics") to commercially exploit the '091 patent in June 2002 (¶ 33). The AAT produced through this method is not glycosylated, as compared to the method of producing AAT through *Pichia pastoris* yeast cells (¶ 34).

According to the TAC, on multiple occasions, Arriva has falsely represented that it has exclusive rights in and/or ownership of the '859 patent, including the ability to make, sell, or use AAT to treat eye or ear infections (including otitis media and otitis externa, in humans or in animals) to investors, customers, and/or users of AlphaMed's AAT technology as claimed in the '859 patent (¶ 57). Additionally, in or about April 2000, Arriva began a collaboration with the University of Florida relating to preclinical research studies associated with AAT (¶ 65). In or about June 2001, Arriva and the University of Florida expanded their collaboration to cover ex-vivo and animal otitis studies using recombinant AAT and SLPI (¶ 65). As part of that collaboration, the University of Florida is receiving funding and/or working with and/or acting on

behalf of Arriva in performing acts that are within the scope of the claims in the '859 patent, including the administration of AAT and SLPI to animals and/or humans afflicted with otitis media (¶ 66). In July 2002, the University of Florida created a budget for these clinical trials and prepared a consent form to be signed by human subjects (¶ 66). According to the TAC, these activities indicate a clear intent to commercialize AAT and SLPI derived pharmaceuticals for the treatment of otitis media or otitis externa upon the receipt of regulatory authorization (¶ 68) and are either active infringement of the '859 or an intent to infringe the '859 patent in the future (¶ 70). The TAC also alleges that Arriva will engage in inevitable future acts, such as stockpiling AAT derived pharmaceuticals and further marketing AAT derived pharmaceuticals for otitis media (¶ 72).

***3** Starting some time prior to January 2003, Arriva put out a series of advertisements on its internet web site, which, according to the TAC, convey a false impression that Arriva has the legal right to commercialize AAT for the treatment of inflammatory ear diseases (¶ 83). In its "Company Profile" webpage of its internet website dated January 13, 2003, Arriva stated that it is a privately held company focused on "the development and commercialization of recombinant protease inhibitors for treatment of a wide range of human diseases." According to the webpage, Arriva's areas of therapeutic focus are, among others, inflammatory ear diseases (¶ 84). In further describing its therapeutic focus in the area of inflammatory ear diseases in its "Inflammatory Ear Diseases" webpage, Arriva states: "Scientists at Arriva, in collaboration with investigators at the University of Florida, are investigating the use of AAT in treating the inflammation seen in childhood and adult ear infections. Otitis media, inflammation of the middle ear, is the most common disease of childhood." (¶ 85).

Starting some time prior to 2001, Arriva prepared and disseminated a series of business summaries and business overviews, which it distributed to potential investors and potential business and venture partners (¶ 97). In one such summary, Arriva stated in a graph that its timeline to conduct clinical trials for use of AAT to treat otitis media was the end of 2001, and that its "FDA Approval Window" for obtaining FDA approval for a drug to treat otitis media using AAT was between 2003 and 2004 (¶ 98). In various drafts of its business overview titled "Protease inhibitor therapeutics for the treatment of inflammatory ear disease," Arriva provides an entire analysis of its therapeutic focus in the area of inflammatory ear disease. In all drafts, Arriva states that its goal is to receive FDA and worldwide approval "for the use of recombinant AAT in the treatment of otitis media and otitis externa." (¶ 99). According to the TAC, these business summaries and overviews convey a false or misleading impression that Arriva has the legal right to commercialize AAT for the treatment of inflammatory ear diseases (¶ 100).

AlphaMed filed the Complaint in this case on January 14, 2003, an Amended Complaint on February 6, 2004, and a Second Amended Complaint on July 26, 2004. Arriva filed the present Motion to Dismiss on September 10, 2004, but AlphaMed filed the TAC, with leave of the Court, on December 17, 2004. The TAC eliminates two counts against Arriva but makes no substantive changes to the remaining allegations against Arriva. Therefore, although Arriva's Motion addresses the Second Amended Complaint, the Court considers the arguments contained in it with respect to the TAC.

In the TAC, AlphaMed alleges seven counts against Arriva: (1) declaratory judgment as to ownership of the '859 patent; (2) declaratory judgment as to infringement of the '859 patent; (3) false advertising relating to Arriva's website; (4) false advertising relating to Arriva's business plans and offering materials; (5) misappropriation of trade secrets; (6) tortious interference with advantageous business relationships; and (7) common law unfair competition. Arriva moves to dismiss all claims except Count 5, misappropriation of trade secrets. [FN5]

> FN5. In its Motion to Dismiss, Arriva moves to dismiss this count as it pertains to documents it alleges are not trade secrets and are not related to AAT. Because the TAC eliminate references to those documents, the Court does not consider this argument.

II. *LEGAL ANALYSIS*

A. *The Standard on a Motion to Dismiss*

***4** For purposes of a motion to dismiss, the court must accept the allegations of the complaint as true. *United States v. Pemco Aeroplex, Inc.*, 195 F.3d 1234, 1236 (11th Cir.1999) (en banc). Moreover, the complaint must be viewed in the light most favorable to the plaintiff. *St. Joseph's Hosp., Inc. v. Hosp. Corp. of America*, 795 F.2d 948, 953 (11th Cir.1986). To warrant a dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure, it must be "clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Blackston v. Alabama*, 30 F.3d 117, 120 (11th Cir.1994) (quoting

Hishon v. King & Spalding, 467 U.S. 69, 73 (1984)). Nonetheless, to survive a motion to dismiss, a plaintiff must do more than merely label his or her claims. *Blumel v. Mylander,* 919 F.Supp. 423, 425 (M.D.Fla.1996). Thus, dismissal of a complaint or a portion thereof is appropriate when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action. *Marshall County Bd. of Educ. v. Marshall County Gas Dist.,* 992 F.2d 1171, 1174 (11th Cir.1993). In deciding a motion to dismiss, a court may only examine the "four corners" of the complaint and any matters incorporated therein, and not matters outside the complaint, without converting the motion to dismiss into a motion for summary judgment. *See Crowell v. Morgan Stanley Dean Witter Servs., Co., Inc.,* 87 F.Supp.2d 1287, 1290 (S.D.Fla.2000); *Blount v. Sterling Healthcare Group, Inc.,* 934 F.Supp. 1365, 1368 (S.D.Fla.1996).

B. *AlphaMed has not stated a claim for declaratory relief for patent infringement in Counts I and II.*

In Count I, AlphaMed seeks a declaration, pursuant to the Declaratory Judgment Act, that it is the owner of the '859 patent. In Count II, AlphaMed seeks a declaration that Arriva is currently and/or will imminently infringe on the '859 patent. Count I is duplicative of Count II because in order to take legal action for patent infringement, a plaintiff needs to have an ownership interest in that patent. In fact, in Count II's prayer for relief, among other things, AlphaMed seeks a declaration that "AlphaMed is the sole owner of the '859 Patent...." *TAC,* p. 21. That is the same relief requested in Count I. Therefore, for purposes of the present Motion, the Court considers Counts I and II together.

The Declaratory Judgment Act, 28 U.S.C. § 2201, provides, in relevant part:

> (a) In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

"[T]he operation of the Declaratory Judgment Act is procedural only." *Household Bank v. JFS Group,* 320 F.3d 1249, 1253 (11th Cir.2003) (quoting *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227 (1937)). If there is an underlying ground for federal court jurisdiction, the Declaratory Judgment Act "allow[s] parties to precipitate suits that otherwise might need to wait for the declaratory relief defendant to bring a coercive action." *Gulf States Paper Corp. v. Ingram,* 811 F.2d 1464, 1467 (11th Cir.1987). "The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual 'controversy' required by the Act." *Lang v. Pacific Marine and Supply Co., Ltd.,* 895 F.2d 761, 764 (Fed.Cir.1990) (citing *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.,* 846 F.2d 731, 735 (Fed.Cir.1988)).

***5** Declaratory judgment actions in the patent area are most commonly brought by potential infringers against patentees seeking a declaration of noninfringement or invalidity or both. *Lang,* 895 at 763 (citing 10A Wright & Miller, Fed. Prac. & Proc. Juris. § 6761). Declarations of infringement sought by patentees against parties who will allegedly infringe in the future have been less frequently requested but have been allowed. *Id.* (citations omitted). To meet the controversy requirement in a declaratory judgment suit by a patentee against an alleged future infringer, two elements must be present: (1) the defendant must be engaged in an activity directed toward making, selling, or using the patented item subject to an infringement charge under 35 U.S.C. § 271(a), or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming. *Id.* Even assuming an actual controversy, the exercise of a court's jurisdiction over a declaratory judgment action is discretionary. *Spectronics Corp. v. H.B. Fuller Co.,* 940 F.2d 631, 634 (Fed.Cir.1991).

The TAC alleges that Arriva has falsely represented that it has exclusive rights in and/or ownership of the '859 patent by representing on its website that "AAT is currently being formulated for its use to treat [otitis media]" (¶ 58), and asserting in answers to interrogatories in this case that "[o]n information and belief, Arriva has rights, title and/or interest in [the '859 patent]" (¶ 59). AlphaMed alleges that Arriva has infringed on the '859 patent by taking the following actions: (1) collaborating with the University of Florida with respect to preclinical research studies associated with AAT (¶ 65); (2) collaborating with the University of Florida on *ex-vivo* and animal otitis studies using recombinant AAT and SLPI (¶ 65); (3) performing clinical trials with AAT and SLPI on animals and/or humans (¶ 66); and (4) publishing research plans, which "indicate a clear intent to commercialize AAT and SLPI derived pharmaceuticals for the treatment of

otitis media or otitis externa, upon the receipt of regulatory authorization" (¶ 68).

Arriva advances two key arguments in the Motion to Dismiss: (1) AlphaMed has not alleged any specific acts that Arriva has taken that indicate either present infringement or imminent future infringement sufficient to warrant declaratory relief; and (2) all of the acts Arriva has taken with respect to its collaboration with the University of Florida are, as a matter of law, non-infringing.

Arriva relies heavily on *Lang,* 895 F.2d 761, to bolster its first argument that there is not an imminent threat of infringement. The plaintiff in *Lang* held patents for several features of a ship's hull and sued for a declaration of future infringement, alleging that the defendants were in the process of manufacturing a hull that, when finished, would infringe on his patents. *Lang,* 895 F.2d at 763. The Federal Circuit held that it lacked subject matter jurisdiction over the claim because the defendants were nine months away from completing the allegedly infringing hull at the time the declaratory judgment action had been filed and had not distributed sales literature or solicited orders for the allegedly infringing hull. *Id.* at 764. Therefore, the plaintiff had not demonstrated a substantial controversy of sufficient immediacy to warrant the court's jurisdiction. *Id.* at 764-65.

***6** According to Arriva, the present case is similar to *Lang* because even if the allegations of the TAC are true, AlphaMed has not alleged that Arriva has a pharmaceutical product or that Arriva is selling an imminent pharmaceutical product. "Without certainty of FDA approval, which AlphaMed cannot allege, Arriva's commercialization activities are not imminent." *Motion to Dismiss,* p. 14; *see also Abbott Laboratories v. Zenith Laboratories,* 934 F.Supp. 925, 938 (N.D.Cal.1995) (FDA approval in three months was not imminent enough to warrant declaratory relief).

AlphaMed argues that *Lang* is inapplicable because Arriva has done more than the defendant did in *Lang.* According to AlphaMed, Arriva has also advertised to investors, through its website, that it has exclusive rights to make AAT to treat eye and ear infections. However, in the TAC, the only specific factual allegation that comes close to such a claim is that Arriva has stated that "AAT is currently being formulated for its use to treat [otitis media]" (¶ 58). And While Arriva also has declared, through discovery requests, that it may have ownership rights to the '859 patent (¶ 57), there are no allegations that Arriva has advertised to anyone that it has exclusive rights to AAT-derived pharmaceuticals other than the blanket allegation that "[o]n multiple occasions ... Arriva has falsely represented that it has exclusive rights in and/or ownership of the '859 Patent...." (¶ 57). Additionally, the TAC acknowledges that Arriva has a license from ZymoGenetics to produce AAT using *Pichia pastoris* yeast cells (¶ 33), but AlphaMed does not distinguish between statements made by Arriva relating to the license from ZymoGenetics, which Arriva does have a license to use, and statements relating to the '859 patent .

AlphaMed additionally argues that *Lang* is inapplicable because it did not deal with the pharmaceutical industry or FDA approval. However, AlphaMed uses another non-pharmaceutical case to bolster its argument. In that case, a court allowed a declaratory action for patent infringement when the defendant had advertised the new product (a microcomputer chip) but had not yet sold or manufactured it. *Automation Systems, Inc. v. Intel Corp.,* 501 F.Supp. 345, 346 (D.Iowa 1980). The court noted that the plaintiff had alleged that the product in question had been widely distributed, samples would soon be available and orders soon solicited. *Id* at 348.

Unlike the plaintiff in *Automation Systems,* AlphaMed has not alleged that Arriva has advertised any infringing product. According to AlphaMed, Arriva has only advertised, on its website, that AAT is currently being formulated to treat otitis media. It is not alleged that Arriva has sold or manufactured anything, nor that Arriva has prepared to sell or manufacture anything. In other words, AlphaMed has not identified an infringing product.

In another case considered by the Federal Circuit dealing with medical devices, the district court declined to exercise jurisdiction over a declaratory judgment action, and the Federal Circuit affirmed, because the defendant, at the time of the suit, had only recently begun clinical trials and was years away from potential FDA approval. *Telectronics Pacing Systems, Inc v. Ventritex, Inc..,* 982 F.2d 1520, 1527 (Fed.Cir.1992). Similarly, Arriva has engaged in clinical trials and collaboration with the University of Florida, but AlphaMed has not alleged that Arriva has sought FDA approval for any particular drug. In fact, AlphaMed has not even alleged that Arriva has developed any drug that *could* gain FDA approval. The TAC contains only generalized allegations that Arriva would like to bring to market, at some unspecified

time, an AAT-derived pharmaceutical, without specifying what the product is, when FDA approval will be sought, or whether or not the hypothetical pharmaceutical will be produced through Arriva's license with ZymoGenetics.

***7** Arriva's second argument relies on a statutory provision that allows a "safe harbor" against patent infringement:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1). This provision ensures that a patentee's rights do not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval. *Integra Lifesciences v. Merck KGaA,* 331 F.3d 860, 865 (Fed.Cir.2003).

Section 271(e)(1) benefits competitors of the patent holder by freeing them from liability for development work reasonably related to securing regulatory approval. By enabling testing to comply with regulatory processes before patent expiration, this section allows competitors to enter the market more quickly after a patent expires, thus limiting what would otherwise amount to an extension of the patent term. *See Glaxo Inc. v. Novopharm Ltd.,* 110 F.3d 1562, 1568 (Fed.Cir.1997). The safe harbor permits "premarket approval activity conducted for the sole purpose of sales after patent expiration." *Hoechst-Roussel Pharms., Inc. v. Lehman,* 109 F.3d 756, 763 (Fed.Cir.1997). For example, clinical trials and demonstrations of medical devices are allowed, *Integra Lifesciences,* 331 F.3d at 865, as is conduct collateral to clinical trials, such as the reporting of preclinical trial progress to investors, analysts, and journalists. *Telectronis Pacing System, Inc. v. Ventritex, Inc.,* 982 F.2d 1520, 1523 (Fed.Cir.1992).

However, the safe harbor does not "reach any exploratory research that may rationally form only a predicate for future FDA clinical tests." *Integra Lifesciences,* 331 F.3d at 867. "Extending § 271(c)(1) to embrace all aspects of new drug development activities would ignore its language and context with respect to the 1984 Act [which granted the safe harbor] in an attempt to exonerate infringing uses only potentially related to information for FDA approval. Moreover, such an extension would not confine the scope of § 271(e)(1) to *de minimis* encroachment on the rights of the patentee." *Id.*

In *Integra,* the defendants' allegedly infringing experiments did not supply information for submission to the FDA but instead identified the best drug candidate to subject to future clinical testing under the FDA processes. *Integra,* 331 F.3d at 867. The defendants' experiments were general biomedical research which identified new pharmaceutical compounds leading to new drug candidates. Although the *Integra* court only considered clinical research conducted to identify potential new drug candidates, the court established the outer limits of the safe harbor provision. The court clarified that infringing activity would only be allowed if it was reasonably related to FDA approval of a current drug. *Id.*

***8** AlphaMed has not alleged that any of the activities Arriva has taken constitute research to identify new drugs that may be subject to FDA approval. Rather, the TAC only contains allegations that Arriva has been conducting clinical trials relating to AAT for use in ear infections, precisely the kind of research that the safe harbor provision protects.

In an attempt to bolster its argument that this case is like *Integra,* AlphaMed states in its response to the Motion to Dismiss:

> [t]o the extent that the University of Florida and Arriva are investigating compositions that would require separate FDA applications (e.g., compositions with and without SLPI or compositions with other significant differences), under the *Integra* case, they are deemed to be outside the scope of the § 271(e)(1) exception, in that they are not simply developing data useful for FDA approval of a drug compound, but are instead trying to discover an appropriate drug composition for which such data can be developed in the future.

Response, p. 7. However, there are no allegations in the TAC that the collaboration between Arriva and the University of Florida has consisted of research into new compositions that would lead to new drugs or FDA approval for different drugs. Rather, AlphaMed has only alleged that Arriva has been conducting pre-clinical trial research and clinical trials relating to AAT and the treatment of ear infections. AlphaMed *does* allege that the present activities of Arriva will lead to "inevitable commercialization activities," but AlphaMed does not allege with any specificity what these activities are and whether they are imminent.

Lastly, AlphaMed argues that "[o]nce regulatory

approval has been granted, the exception created by 35 U.S.C. § 271(e)(1) will no longer protect the activities of Arriva...." (¶ 73). AlphaMed thus seems to concede that the current activities of Arriva are protected by the safe harbor provision, and that future activities, which are not defined, will not be. AlphaMed has made only conclusory allegations that Arriva will inevitably participate in non-exempt infringing acts prior to obtaining regulatory approval, such as stockpiling AAT pharmaceuticals. AlphaMed's allegations are purely speculative; AlphaMed has failed to allege any facts demonstrating that this "inevitable" conduct is real and imminent. [FN6] Therefore, AlphaMed has not stated a claim under the Declaratory Judgment Act for present or future infringement.

> FN6. At oral argument, counsel for AlphaMed stated that the safe harbor provision could be used as an affirmative defense, but it could not be a ground to dismiss the TAC. However, from the face of the TAC, the Court is able to determine that the complained-of activities are protected by the safe harbor provision, as a matter of law.

C. *AlphaMed has not stated claims for false advertising in Counts III and IV.*

In Count III, AlphaMed alleges that Arriva has violated Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a) by placing a series of false or misleading advertisements on its internet web site. These advertisements, according to AlphaMed, are literally true or ambiguous but misleading because they convey a false impression that Arriva has the legal right to commercialize AAT for the treatment of inflammatory ear diseases (¶ 83). On its "Company Profile" webpage, Arriva stated that it is a privately held company focused on "the development and commercialization of recombinant protease inhibitors for treatment of a wide range of human diseases," including inflammatory ear diseases (¶ 84). In its "Inflammatory Ear Diseases" webpage, Arriva stated that "Scientists at Arriva, in collaboration with investigators at the University of Florida, are investigating the use of AAT in treating the inflammation seen in childhood and adult ear infections" (¶ 85).

***9** In Count IV, AlphaMed alleges that Arriva has violated the Lanham Act by disseminating a series of misleading advertisements in the form of "business summaries" and "business overviews" to potential investors and business and venture partners (¶ 97). In one business summary, Arriva stated in a timeline graph that its timeline to conduct clinical trials for the use of AAT to treat otitis media was the end of 2001 and that its "FDA Approval Window" for obtaining FDA approval of a drug to treat otitis media using AAT was between 2003 and 2004 (¶ 98). In various drafts of its business overview titled "Protease inhibitor therapeutics for the treatment of inflammatory ear disease," Arriva provides an entire analysis of its therapeutic focus in the area of inflammatory ear disease. In every draft, Arriva states that its goal is to receive FDA and worldwide approval "for the use of recombinant AAT in the treatment of otitis media and otitis externa" (¶ 99).

Section 43(a) of the Lanham Act provides, in pertinent part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which ... (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a). To state a false advertising claim under § 43(a)(1)(B) of the Lanham Act, a plaintiff must allege: (1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented product or service affects interstate commerce; and (5) the plaintiff has been, or is likely to be, injured as a result of the false advertising. *Hickson Corp. v. Northern Crossarm Co., Inc.*, 357 F.3d 1256, 1260 (11th Cir.2004) (citations omitted). The first element of the Lanham Act test requires that the plaintiff show that the statements at issue were either "(1) commercial claims that are literally false as a factual matter" or "(2) claims that may be literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or likely to deceive consumers." *Id.* at 1261 (quoting *United Industries Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir.1998)).

AlphaMed has alleged: (1) Arriva's statements on its website and business plans are misleading (¶¶ 83; 97); (2) Arriva's statements had the capacity to deceive future investors in AlphaMed and Arriva (¶¶ 86; 100);

(3) Arriva's deceptive statements materially affected investors in AlphaMed (¶¶ 90; 104); (4) the statements and the underlying claims affected interstate commerce (¶¶ 81; 105); and (5) AlphaMed has been injured and will be further injured in the future as a result of Arriva's misleading statements (¶¶ 92; 106).

***10** Arriva challenges the sufficiency of these allegations on three grounds. First, Arriva argues that AlphaMed lacks standing to make a Lanham Act false advertising claim because AlphaMed does not have a present or imminent AAT drug on the market, making its claims hypothetical. Second, Arriva argues that AlphaMed's false advertising claims are not premised on false or misleading representations in connection with any goods or services because neither AlphaMed nor Arriva has an actual AAT pharmaceutical product on the market. Finally, Arriva argues that its representations on its website and business plans are actually true and not misleading because they do not convey an impression that Arriva has a patent, a patent application, or a license to use AAT to treat inflammatory ear diseases.

The Third Circuit has developed a test for determining whether a plaintiff has standing to bring a false advertising claim under the Lanham Act. *Conte Bros. Auto., Inc. v. Quaker State-Slick 50, Inc.,* 168 F.3d 221 (3d Cir.1998). In that case, the plaintiffs were "a putative nationwide class of retail sellers of motor oil and other engine lubricants that purportedly compete[d] with Slick 50, a Teflon-based engine lubricant manufactured by [defendants]." *Id.* at 223-24. In other words, whereas the defendants manufactured engine lubricant, the plaintiffs sold the same type of product, though not the defendants' brand. The retailers alleged that the defendants "falsely advertised that the addition of Slick 50 would reduce the friction of moving parts, decrease engine wear, and improve engine performance efficiency." *Id.* at 224.

The Third Circuit began its standing analysis by recognizing that at the time "there exist[ed] no single overarching test for determining the standing to sue" under § 43(a). *Id.* According to the Third Circuit, in order to determine whether a plaintiff has standing to assert a false advertising claim under the Lanham Act, the court considers: (1) whether the injury alleged is "of a type that Congress sought to redress in providing a private remedy for violations of the [Lanham Act]"; (2) the directness or indirectness of the asserted injury; (3) the proximity or remoteness of the party to the alleged injurious conduct; (4) the speculativeness of the damages claim; and (5) the risk of duplicative damages or complexity in apportioning damages. *Conte Bros.,* 165 F.3d at 233 (citing *Associated Gen. Contractors,* 459 U.S. at 538- 44).

As to the first factor (whether the plaintiff's asserted injury is "of a type the Congress sought to redress"), the Lanham Act has two aims: (1) vindicating " 'commercial interests [that] have been harmed by a competitor's false advertising"; and (2) " 'secur[ing] to the business community the advantages of reputation and good will by preventing their diversion from those who have created them to those who have not." ' *Id.* at 234 (citations omitted). The Third Circuit found that the rectification of the injury asserted by the plaintiff class furthered neither of these purposes. *Id.* Although the harm asserted by the retailers was commercial, it was not competitive in nature. The retailers asserted that the defendants' misrepresentations resulted in pecuniary losses for their business enterprises (thereby rendering the injury commercial), but they did not contend that they incurred such losses because those representations impugned them as vendors of engine additive or, conversely, touted the virtues of any competing retailer. *Id.*

***11** In the present case, AlphaMed has alleged that it is a competitor of Arriva and that its commercial interests will be harmed by Arriva's alleged false advertising. Arriva argues, however, that AlphaMed has not alleged that either AlphaMed or Arriva has an AAT-derived pharmaceutical on the market or will imminently have one on the market. Therefore, according to Arriva, AlphaMed's alleged injury is not of the type of competitive injury Congress sought to address.

To bolster its standing argument, Arriva heavily relies on a Second Circuit case with similar facts. In *PDK Labs, Inc. v. Friedlander,* 103 F.3d 1105 (2d Cir.1997) , a retailer of weight loss products brought a declaratory judgment action against a patentee of a method for inducing weight loss by administering a combination of ephedrine, caffeine, and aspirin ("ECA"), seeking a declaration that the patentee did not have standing to sue under Lanham Act's false advertising provision. *PDK,* 103 F.3d at 1107. The patentee was not selling an ECA weight loss product to the public at the time of the alleged injury. Rather, he was marketing his product to potential investors to raise funds needed to commercialize an ECA weight loss product and to obtain FDA approval. *Id.* The Second Circuit held that the patentee had no standing to sue because he "does not currently sell a retail weight loss product that competes with [the retailer's]

products. *Id.* at 1112. "Although a future 'potential for a commercial or competitive injury' can establish standing ... Friedlander's [the patentee's] hopes of eventually obtaining FDA approval and selling a retail weight loss product are too remote at this stage to confer standing to challenge [the retailer's] advertising." *Id.* (citations omitted).

Like the patentee in *PDK,* AlphaMed has alleged that it holds a patent but it has not alleged that it has an imminent AAT product for eye and ear infections, nor has it alleged that it has sought FDA approval of any product. AlphaMed attempts to distinguish *PDK* by pointing out that the patentee in that case was unable to assert that he was a competitor of the retailer *only* because the retailer entered the market without obtaining FDA approval for its product. In the present case, both Arriva and AlphaMed *have* asserted that they are competitors of each other, each attempting to bring to market an AAT-derived pharmaceutical for the treatment of car infections before the other. Therefore, according to AlphaMed "[i]t would be incongruous for Arriva to now try to argue that the two companies are not competitors after all." *Response,* p. 8. However, AlphaMed has not alleged that it has a specific product that competes with a product of Arriva's. Like the patentee in *PDK,* it only has a speculative product, and it is only alleging injury through loss of investors, not consumers.

AlphaMed cites other cases in its response for the proposition that if Arriva and AlphaMed are considered competitors in general, then the absence of a competing product on the market or about to be on the market is immaterial. Arriva correctly points out that in both cases cited by AlphaMed, the parties were selling actual products that competed, even if the specific products in question were not directly competing. In *Johnson & Johnson v. Carter-Wallace, Inc.,* 631 F.2d 186 (2d Cir.1980), the parties were selling actual products that competed in the hair removal market, Nair and Baby Oil, and not simply speculative products. Although Nair and Baby Oil were not competitive products in the specific depilatory market, the goods competed in the general hair removal market. In *National Basketball Ass'n v. Motorola, Inc.,* 105 F.3d 841 (2d Cir.1997), the NBA did not have a product on the market in competition with Motorola's product, a pager providing real-time sporting event information. Therefore, the court dismissed the NBA's claim for false advertising.

***12** In this case, AlphaMed has not alleged that either party actually has an AAT-derived pharmaceutical product currently on the market; according to the TAC, both parties are attempting to bring to market such products. The TAC does not focus on consumer confusion due to the alleged false advertising. Instead, the allegations deal with *investor* confusion, namely, that Arriva's representations on its website and in its business plans create the false impression that it has a patent similar to the '859 patent. AlphaMed, as the holder of the patent, complaints of false advertising which affects investment in its company, which holds the '859 patent. AlphaMed and Arriva compete in the market for investors, who will allow each to bring to market an AAT-derived pharmaceutical for the treatment of ear infections. However, because no allegation of *consumer* confusion has been made, nor could it, since there is no product alleged to exist on the market, AlphaMed has no standing to sue under the Lanham Act's false advertising provision. *See Telecom Intern. America, Ltd. v. AT & T Corp.,* 280 F.3d 175, 197 (2d Cir.2001) ("Because AT & T's alleged misrepresentations were made in its role as an equipment and service provider to a reseller, rather than in its later-acquired role of a call-turnaround provider to ultimate consumers, AT & T and TIA were not competitors when the alleged false statements were made."); *see also PDK,* 103 F.3d at 1112.

In fact, like the patentee in *PDK,* AlphaMed has not alleged that it has *any* products on the market. AlphaMed is alleging that it is marketing its future AAT product to potential investors so that it can raise funds needed to continue research and receive FDA approval. AlphaMed is in the same position as the patentee in *PDK* and does not have standing under the Lanham Act.

Arriva's second argument, that AlphaMed's claims are defective because they are not premised on false or misleading representations in connection with any goods or services, is related to the standing argument. According to Arriva, because *Arriva* does not have an AAT-derived pharmaceutical product on the market for the treatment of ear and eye infections, the statements it made on its website and on business plans cannot be connected to any "goods or services." *See* 15 U.S.C. § 1125(a)(1)(B). AlphaMed counters that the phrase "goods or services" in the Lanham Act is meant to limit claims to misleading advertising involving commercial speech. While neither Arriva nor AlphaMed has a product in the market yet, Arriva is promoting AAT-related services in developing such a product, which is commercial speech.

Although the Eleventh Circuit has not articulated a test

to determine whether misrepresentations constitute "commercial advertising or promotion" within the meaning of the Lanham Act, other circuits have:

> In order for representations to constitute "commercial advertising or promotion" under Section 43(a)(1)(B), they must be: (1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services. While the representations need not be made in a "classical advertising campaign," but may consist instead of more informal types of "promotion," the representations (4) must be disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry.

***13** *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379 (5th Cir.1996) (adopting the test set forth in *Gordon & Breach Sci. Publishers v. Am. Inst. of Physics*, 859 F.Supp. 1521, 1535-36 (S.D.N.Y.1994)). This test has been adopted by several circuit courts of appeals and district courts. *See Procter & Gamble, Co. v. Haugen*, 222 F.3d 1262, 1273-74 (10th Cir.2000); *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir.1999); *but cf. Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 58 (2d Cir.2002)(adopting the first, third and fourth elements of the *Gordon & Breach* test, but declining to express an opinion on whether misrepresentations in "commercial advertising and promotion" must be made by a defendant in commercial competition with the plaintiff). The *Seven-Up* court concluded that, "[w]e find this summary of the requirements for establishing 'commercial advertising or promotion' under § 43(a) of the Lanham Act both accurate and sound." *Seven-Up*, 86 F.3d at 1384.

The alleged speech is commercial speech, and AlphaMed alleges that Arriva is its competitor. Therefore, the first two prongs of the *Gordon & Breach* test are satisfied. The speech, however, was not made to influence consumers to purchase products of Arriva. As previously stated, neither party has an AAT-derived pharmaceutical on the market, and no consumers are involved with the allegations made in the TAC. The alleged speech was not made to a purchasing public. Therefore, all the allegations show is that the statements are in connection with *potential* goods and relate to commercial speech, but because there is no product at issue, they are not related to "goods and services" as defined by the Lanham Act and articulated by the *Gordon & Breach* test.

At oral argument, counsel for AlphaMed stated that Arriva and AlphaMed compete with regard to commercial activities, which counsel claimed is a category of activity encompassed by the statute. However, the text of the statute is clear: a defendant is liable when it engages in activities that are "on or in connection with any goods or services." 15 U.S.C. § 1125(a)(1). The "commercial activities" to which counsel refers are, presumably, the "commercial advertising" and "promotion" in which a defendant might engage. 15 U.S.C. § 1125(a)(1)(B). In other words, a defendant might engage in commercial activities that subject it to liability, but those commercial activities must be in connection with goods or services. AlphaMed has alleged that Arriva and AlphaMed are competitors with respect to generalized commercial activities. To have standing for a false advertising claim under the Lanham Act, however, a plaintiff must allege more: a plaintiff must allege that the suspect commercial activities were related to some specific good or service, and AlphaMed has not done that.

Arriva's final argument centers on the purported truth of the statements made. However, AlphaMed has not claimed that the statements are literally false; instead, AlphaMed alleges that they are misleading. A false advertising claim may be maintained if the challenged statements are literally false or literally true, but misleading. *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1247 (11th Cir.2002). A plaintiff attempting to establish the second kind of falsehood, that an advertisement is literally true but misleading, must "present evidence of deception" in the form of consumer surveys, market research, expert testimony, or other evidence. *Id.* Consumer survey research often is a key part of a Lanham Act claim alleging that an advertisement is misleading or deceptive. *See Johnson & Johnson*Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir.1992) ("[T]he success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a consumer survey.").

***14** At the pleading stage, AlphaMed is not required to submit this evidence. It is sufficient for AlphaMed to allege that the statements are deceptive. Nonetheless, because it does not have standing, AlphaMed has not stated claims for false advertising under the Lanham Act in Counts III and IV.

D. *AlphaMed has stated a claim for tortious interference in Count VI.*

Count VI alleges that Arriva interfered with AlphaMed's business relationship with Williams, AlphaMed's chief investor (¶ 124). According to the TAC, Arriva's officers met with FBI Agent James R. Conner, III ("Agent Conner") to encourage him to target AlphaMed's investors in an investigation of AlphaMed (¶ 125). Agent Conner acted as Arriva's agent and contacted Williams in order to convince him not to continue his business relationship with AlphaMed (¶¶ 126- 129).

To prevail on a tortious interference claim, a plaintiff must show: (1) the existence of a business relationship; (2) the defendant had knowledge of the relationship; (3) the defendant intentionally and unjustifiably interfered with the relationship; and (4) the plaintiff suffered damage as a result. *See Gregg v. U.S. Indus., Inc.*, 887 F.2d 1462, 1473 (11th Cir.1989); *Tamiami Trail Tours, Inc. v. J.C. Cotton*, 463 So.2d 1126, 1127 (Fla.1985). Intentional interference requires both the intent to damage the business relationship and a lack of justification for doing so. *See Smith v. Emery Air Freight Corp.*, 512 So.2d 229, 230 (Fla. 3d DCA 1987) (citing *Landry v. Hornstein*, 462 So.2d 844 (Fla. 3d DCA 1985)). To be intentional, interference need not be motivated by the intent to secure a business advantage. It is enough for the interference to have been motivated by malice; it need not have been motivated by greed. *See Ahern v. Boeing Co.*, 701 F.2d 142, 145 (11th Cir.1983); *Tamiami Trail Tours*, 463 So.2d at 1127-28. AlphaMed has alleged: (1) it had a business relationship with Williams; (2) Arriva had knowledge of the relationship; (3) Arriva acted with malice by inducing Williams not to continue his business relationship with AlphaMed; and (4) as a result, AlphaMed suffered economic damages.

Arriva argues that a tortious interference claim cannot be based on conduct that indirectly or consequentially interfered with the contractual or business relationship at issue. *See Ethyl Corp. v. Balter*, 386 So.2d 1220, 1224 (Fla. 3d DCA 1980) (no claim for interference with contract because the alleged interference was consequential and only indirectly caused the termination of the contract at issue). According to Arriva, AlphaMed's allegations are too attenuated to be sufficient. Arriva claims that an FBI agent's investigation of AlphaMed cannot be the basis for a tortious interference with contract claim. However, AlphaMed specifically alleges that Agent Conner was acting as the agent of Arriva and that Arriva specifically induced Agent Conner to contact Williams, AlphaMed's chief investor. Therefore, the allegations are sufficient to state a claim.

***15** Arriva also argues that the communications made by Agent Conner were qualifiedly privileged because they were done in the course of the FBI's investigation into criminal activity. A statement "made by one who has a duty or interest in the subject matter to one who has a corresponding duty or interest" is qualifiedly privileged. *McCurdy v. Collis*, 508 So.2d 380, 382 (Fla. 1st DCA 1987). In order to assert a qualified privilege, the party seeking to assert it must prove: (1) good faith; (2) an interest to be upheld; (3) a statement limited in its scope to the purpose; (4) a proper occasion; and (5) publication in a proper manner. *See Axelrod v. Califano*, 357 So.2d 1048, 1051 (Fla. 1st DCA 1978) (setting forth the elements of a qualified privilege in the defamation context). A party's privilege to interfere with a business relationship is not qualified where the party purposefully interferes or acts egregiously against another party. *Ernie Haire Ford, Inc. v. Ford Motor Co.*, 260 F.3d 1285, 1294 n. 9 (11th Cir.2001). A qualified privilege does not exist where the sole reason for interference in a contract is to do harm or for some other bad motive. *Id.*

AlphaMed has alleged that Arriva did not act in good faith and that Arriva had no interest with Williams to uphold. AlphaMed has alleged that Arriva's actions were done with malice. Therefore, it has stated a claim for tortious interference with business relationship and has alleged that Arriva's actions are not qualified.

E. *AlphaMed has stated a claim for unfair competition in Count VII.*

In Count VII, AlphaMed alleges that Arriva engaged in common law unfair competition. To establish a claim for unfair competition, Florida law "requires that [plaintiff] establish deceptive or fraudulent conduct of a competitor and likelihood of consumer confusion." *Donald Frederick Evans and Assoc. v. Continental Homes, Inc.*, 785 F.2d 897, 914 (11th Cir.1986). AlphaMed has alleged that Arriva's practices, including corporate espionage, advertising, and relations with investors, constitute deceptive conduct. AlphaMed further alleges that Arriva's claims that it will produce an AAT-derived pharmaceutical will lead to consumer confusion.

Arriva claims that the unfair competition count is preempted by Florida's Uniform Trade Secret Act (the "UTSA"), Fla. Stat. § 688.008, which bars civil claims based upon the misappropriation of trade secrets. Arriva does not otherwise challenge the sufficiency of Count VII. Section 688.008, Fla. Stat., provides:

(1) Except as provided in subsection (2), ss. 688.001-688.009 displace conflicting tort, restitutory, and other law of this state providing civil remedies for misappropriation of a trade secret.
(2) This act does not affect:
(a) Contractual remedies, whether or not based upon misappropriation of a trade secret;
(b) Other civil remedies that are not based upon misappropriation of a trade secret; or
***16** (c) Criminal remedies, whether or not based upon misappropriation of a trade secret.

The UTSA preempts all claims based on misappropriation of trade secrets. *Allegiance Healthcare Corp. v. Coleman,* 232 F.Supp.2d 1329, 1335 (S.D.Fla.2002). In the context of applying the UTSA's preemption provision, the court in *Coulter Corp. v. Leinert,* 869 F.Supp. 732, 734 (E.D.Mo.1994) applied Florida law. In *Coulter,* the court considered the plaintiff's claims for unfair competition and accounting. That court noted the lack of Florida jurisprudence on the statute and interpreted the statute in light of the plain language. *Id.* After doing so, the court concluded that "the plain language clearly precludes common law claims based on a theory of misappropriation of trade secrets. Thus, the issue becomes whether allegations of trade secret misappropriation alone comprise the underlying wrong; if so, the cause of action is barred by § 688.008." *Id.*

Following this rationale, the Court must consider whether AlphaMed's allegations of unfair competition are distinguishable from the allegations of trade secret misappropriation. *See Allegiance Healthcare Corp.,* 232 F.Supp.2d at 1336 (finding that the plaintiff's unfair competition claim based on defendant's use of plaintiff's trade secrets and confidential information and was therefore preempted by the UTSA). AlphaMed incorporates the same general allegations into Count VII (unfair competition) and Count V (theft of trade secrets), but AlphaMed does not incorporate the allegations of Count V into Count VII. In its general allegations, AlphaMed claims that Arriva engaged in corporate espionage, and the theft of trade secrets is included in those allegations. In Count VII, in addition to the general allegations, AlphaMed also incorporates paragraphs 122-130, the allegations dealing with Count VI, tortious interference with business relationships. There are no other specific allegations. Although there are common factual allegations in Counts V and VII, AlphaMed is correct that it does not specifically allege that the misappropriation of trade secrets forms the basis of the unfair competition claim. Therefore, the UTSA does not preempt AlphaMed's unfair competition claim, and AlphaMed has stated a claim for common law unfair competition.

III. *CONCLUSION*

For the all the reasons stated above, it is

ORDERED AND ADJUDGED as follows:
(1) Defendant, Arriva Pharmaceuticals, Inc.'s Motion to Dismiss the Second Amended Complaint (D.E.289) is GRANTED IN PART AND DENIED IN PART as follows:
(a) GRANTED as to Counts I-IV. Counts I-IV are DISMISSED WITHOUT PREJUDICE.
(b) DENIED as to Counts VI and VII.
(2) Plaintiff, AlphaMed Pharmaceuticals, Inc. may file a Fourth Amended Complaint on or before January 25, 2005.

DONE AND ORDERED.

Not Reported in F.Supp.2d, 2005 WL 357326 (S.D.Fla.), 18 Fla. L. Weekly Fed. D 198

Motions, Pleadings and Filings (Back to top)

. 2004 WL 2925022 (Trial Motion, Memorandum and Affidavit) John Lezdey's Reply to Arriva Pharmaceuticals, Inc.'s Memorandum in Opposition to John Lezdey's Emergency Motion for Protective Order (Nov. 05, 2004)

. 2004 WL 2925019 (Trial Motion, Memorandum and Affidavit) Arriva Pharmaceuticals, Inc.'s Memorandum in Opposition to John Lezdey's "Emergency" Motion for Protective Order (Nov. 04, 2004)

. 2004 WL 2925014 (Trial Motion, Memorandum and Affidavit) Alphamed's Response to Defendant Arriva Pharmaceuticals, Inc.'s Motion to Dismiss Second Amended Complaint (Oct. 29, 2004)

. 2004 WL 2925016 (Trial Motion, Memorandum and Affidavit) John Lezdey's Emergency Motion for Protective Order and Supporting Memorandum of Law (Oct. 29, 2004)

. 2004 WL 2925010 (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply to Arriva's Memorandum in Opposition to Plaintiff's Amended Motion for Protective Order (Oct. 25, 2004)

. 2004 WL 2925006 (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply to Defendant Spinelli

Corporation's Response to Plaintiff's Amended Motion for Protective Order (Oct. 19, 2004)

. 2004 WL 2925001 (Trial Motion, Memorandum and Affidavit) Defendant Spinelli's Response to Plaintiffs' Amended Motion for Protective Order to Prevent the Disclosure of Attorney Client and Work Product Privileged Information (Oct. 12, 2004)

. 2004 WL 2925000 (Trial Motion, Memorandum and Affidavit) Defendant Arriva's Memorandum in Opposition to Plaintiff's Amended Motion for Protective Order (Oct. 08, 2004)

. 2004 WL 2924997 (Trial Motion, Memorandum and Affidavit) Spinelli Corporation's Reply to Alphamed's Response to Motion to Dismiss Counts VIII and IX of Second Amended Complaint, Motion to Strike and Memorandum of Law in Support Hereof (Sep. 15, 2004)

. 2004 WL 2924995 (Trial Motion, Memorandum and Affidavit) Defendant Arriva Pharmaceuticals, Inc.'s Motion to Dismiss the Second Amended Complaint (with Incorporated Memorandum of Law)%n1%n (Sep. 10, 2004)

. 2004 WL 2924991 (Trial Motion, Memorandum and Affidavit) Alphamed's Response to Defendant Spinelli Corp.'s Corrected Motion to Dismiss with Prejudice Counts VIII and IX of Second Amended Complaint and Motion to Strike (Sep. 07, 2004)

. 2004 WL 2924986 (Trial Motion, Memorandum and Affidavit) Defendants Ctg and Transeth's Motion to Dismiss with Prejudice Counts VIII and IX of Plaintiff's Second Amended Complaint and Memorandum of Law (Aug. 25, 2004)

. 2004 WL 2924983 (Trial Motion, Memorandum and Affidavit) Defendant Spinelli Corporation's Motion to Dismiss with Prejudice Counts VIII and IX of Second Amended Complaint, Motion to Strike and Memorandum of Law in Support Hereof (Aug. 10, 2004)

. 2004 WL 2924980 (Trial Pleading) Second Amended Complaint for Injunctive Relief and Damages (Jul. 26, 2004)

. 2004 WL 2924970 (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply to Defendant Spinelli Corporation's Response to Plaintiff's Motion for Protective Order (Jul. 23, 2004)

. 2004 WL 2924974 (Trial Motion, Memorandum and Affidavit) John, Jarrett, Noreen and Darren Lezdey and Jamie Holding Company, LLC' Reply to Defendant Spinelli Corporation's Response to Motion to Intervene (Jul. 23, 2004)

. 2004 WL 2924960 (Trial Motion, Memorandum and Affidavit) Defendant Spinelli's Memorandum of Law in Response to Plaintiffs' Motion for Protective Order and in Response to Motion to Intervene (Jul. 20, 2004)

. 2004 WL 2924966 (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply to Arriva's Response in Opposition to Plaintiff's Motion for Protective Order to Prevent the Disclosure of Attorney-Client and Work Product Privileged Information (Jul. 20, 2004)

. 2004 WL 2924957 (Trial Motion, Memorandum and Affidavit) Defendant Arriva's Response in Opposition to Plaintiff's Motion for Protective Order to Prevent the Disclosure of Attorney-Client and Work Product (Jul. 13, 2004)

. 2004 WL 2924950 (Trial Motion, Memorandum and Affidavit) Defendant's Response to Plaintiff's Motion to Compel Production of Documents Listed on Defendant's Privilege Log and for Sanctions with Incorporated Memorandum of Law (Jul. 07, 2004)

. 2004 WL 2924954 (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply to Defendant Arriva's Response to Plaintiff's Motion to Compel Production of Documents Listed on Defendant's Privilege Log and for Sanctions with Incorporated Memorandum of Law (Jun. 14, 2004)

. 2004 WL 2924946 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion to Compel Production of Documents Isted on Defendant's Privilege Log and for Sanctions with Incorporated Memorandum of Law (May. 18, 2004)

. 2004 WL 2924938 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response to Defendant Arriva's Objections to the April 20, 2004 Order Compelling Defendant to Produce Documents Responsive to Plaintiff's Fifth Request for Production (May. 10, 2004)

. 2004 WL 2924929 (Trial Motion, Memorandum and Affidavit) Defendants Ctg and Transeth's Motion to Dismiss Counts IV and V of Plaintiff's Amended Complaint for Injunctive Relief and Damages

(Corrected). Motion for a More Definite Statement, or Motion to Strike (Apr. 30, 2004)

. 2004 WL 2924909 (Trial Motion, Memorandum and Affidavit) Defendant Spinelli Corporation's Motion to Dismiss with Prejudice Count IV (Rico Count) of Amended Complaint and Memorandum of Law in Support Hereof (Apr. 28, 2004)

. 2004 WL 2924912 (Trial Motion, Memorandum and Affidavit) Arriva's Motion to Dismiss Amended Complaint (Apr. 28, 2004)

. 2004 WL 2924916 (Trial Motion, Memorandum and Affidavit) Arriva's Correct Motion to Dismiss Amended Complaint (To Insert Date of Certificate of Service and change "seven causes of action" to "six causes of action" in paragraph I.) (Apr. 28, 2004)

. 2004 WL 2924902 (Trial Motion, Memorandum and Affidavit) Defendant's Reply in Support of its "Unopposed" Motion for Modification/Clarification of Protective Order (Apr. 07, 2004)

. 2004 WL 2924905 (Trial Motion, Memorandum and Affidavit) Plaintiff's Reply to Defendant's Response to Plaintiff's Motion to Compel Defendant to Produce All Responsive Documents in Accordance with Plaintiff's Fifth Request for Production and Incorporated Memorandum of Law (Apr. 07, 2004)

. 2004 WL 2924899 (Trial Motion, Memorandum and Affidavit) Plaintiff Alphamed Pharmaceuticals Corp.'s Response to Defendant's "Unopposed" Motion for Modification/Clarification of Protective Order (Mar. 30, 2004)

. 2004 WL 2924895 (Trial Motion, Memorandum and Affidavit) Defendant's Response to "Plaintiff's Motion to Compel Defendant to Produce all Responsive Documents in Accordance with Plaintiff's Fifth Request for Production and Incorporated Memorandum of Law" (Mar. 29, 2004)

. 2004 WL 2924891 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion to Compel Defendant to Produce all Responsive Documents in Accordance with Plaintiff's Fifth Request for Production and Incorporated Memorandum of Law (Mar. 05, 2004)

. 2004 WL 2924884 (Trial Motion, Memorandum and Affidavit) Alphamed's Reply to Defendant's Response in Opposition to Alphamed's Motion to Compel and for Sanctions (Feb. 19, 2004)

. 2004 WL 2924880 (Trial Pleading) Amended Complaint for Injunctive Relief and Damages (Corrected) (Feb. 11, 2004)

. 2004 WL 2924874 (Trial Pleading) Amended Complaint for Injunctive Relief and Damages (Feb. 06, 2004)

. 2004 WL 2924877 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion for Protective Order and Supporting Memorandum of Law (Feb. 06, 2004)

. 2004 WL 2924873 (Trial Motion, Memorandum and Affidavit) Defendant's Response to Plaintiff's Motion to Compel (Jan. 27, 2004)

. 2004 WL 2924872 (Trial Motion, Memorandum and Affidavit) Defendant's Objections to, and Motion to Quash, "Plaintiff's Notice of Taking Deposition Duces Tecum" (Jan. 15, 2004)

. 2004 WL 2924871 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion to Compel Defendant to Produce all Responsive Documents in Accordance with Plaintiff's First and Second Requests to Produce, Defendant's Initial Disclosures and Motion for Sanctions with Incorporated Memorandum of Law (Jan. 2004)

. 2003 WL 23937095 (Trial Motion, Memorandum and Affidavit) Defendant's Reply in Support of Motion to Compel Responses to First Request for Production of Documents (Dec. 09, 2003)

. 2003 WL 23937085 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response to Defendant's Motion to Compel Responses to First Request for Production of Documents with Supporting Memorandum of Law (Nov. 17, 2003)

. 2003 WL 23937078 (Trial Motion, Memorandum and Affidavit) Defendant's Response to Plaintiff's Motion to Compel Defendant to Comply with Initial Disclosures and for Sanctions (Oct. 27, 2003)

. 2003 WL 23937069 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response to Emergency Motion to Stay Discovery Pending Resolution of Appeal of Magistrate's Denial of Motion for Reconsideration and Alternative Motion for Protective Order (Oct. 22, 2003)

. 2003 WL 23937059 (Trial Motion, Memorandum and

Affidavit) Defendant's Reply in Support of Motion to Stay Discovery Pending Resolution of Appeal of Magistrate's Denial of Motion for Reconsideration and Alternative Motion for Protective Order (Oct. 20, 2003)

. 2003 WL 23937049 (Trial Motion, Memorandum and Affidavit) Defendant's Emergency Motion to Stay Discovery Pending Resolution of Appeal of Magistrate's Denial of Motion for Reconsideration and Alternative Motion for Protective Order (Oct. 17, 2003)

. 2003 WL 23937032 (Trial Motion, Memorandum and Affidavit) Defendant's Reply in Support of Appeal of Magistrate's Denial of Motion for Reconsideration and Alternative Motion for Protective Order (Oct. 15, 2003)

. 2003 WL 23937008 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response to Defendant's Motion to Stay Discovery Pending Resolution of Appeal of Magistrate's Denial of Motion for Reconsideration and Alternative Motion for Protective Order with Incorporated Memorandum of Law (Oct. 10, 2003)

. 2003 WL 23937022 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion to Compel Defendant to Comply with Initial Disclosures and for Sanctions with Incorporated Memorandum of Law (Oct. 10, 2003)

. 2003 WL 23936998 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response to Defendant's Appeal of Magistrate Judge's Denial of Motion for Reconsideration and Alternative Motion for Protective Order With Incorporated Memorandum of Law (Oct. 07, 2003)

. 2003 WL 23936986 (Trial Motion, Memorandum and Affidavit) Defendant, Arriva Pharmaceuticals, Inc.'s Appeal of Magistrate Judge's Denial of Motion for Reconsideration and Alternative Motion for Protective Order (Sep. 22, 2003)

. 2003 WL 23936977 (Trial Motion, Memorandum and Affidavit) Defendant's Motion to Compel Responses to First Request for Production of Documents With Supporting Memorandum of Law (Sep. 18, 2003)

. 2003 WL 23936966 (Trial Motion, Memorandum and Affidavit) Defendant, Arriva Pharmaceuticals, Inc.'s Reply in Support of Motion for Reconsideration and Alternative Motion for Protective Order (Aug. 28, 2003)

. 2003 WL 23936957 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response to Defendant's Motion for Reconsideration and Alternative Motion for Protective Order and Incorporated Memorandum of Law (Aug. 21, 2003)

. 2003 WL 23936944 (Trial Motion, Memorandum and Affidavit) Defendant, Arriva Pharmaceuticals, Inc.'s Motion for Reconsideration and Alternative Motion for Protective Order (Aug. 05, 2003)

. 2003 WL 23936934 (Trial Motion, Memorandum and Affidavit) Defendant, Arriva Pharmaceuticals, Inc.'s Response to Plaintiff's Motion to Strike Defendant's Supplemental Authority (Aug. 04, 2003)

. 2003 WL 23936922 (Trial Motion, Memorandum and Affidavit) Defendant, Arriva Pharmaceuticals, Inc.'s Reply in Support of Motion for Protective Order and/or to Quash as to Amended Subpoena Duces Tecum to University of Florida Records Custodian (Jul. 14, 2003)

. 2003 WL 23936917 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion to Strike Defendant's Supplemental Authority and Incorporated Memorandum of Law (Jul. 09, 2003)

. 2003 WL 23936910 (Trial Motion, Memorandum and Affidavit) Plaintiff Alphamed Pharmaceuticals Corp.'s Response to Defendant Arriva Pharmaceuticals Inc.'s Motion for Protective Order and/or Motion to Quash as to Amended Subpoena Duces Tecum to University of Florida Records Custodian (Jun. 26, 2003)

. 2003 WL 23936904 (Trial Motion, Memorandum and Affidavit) Plaintiff Alphamed Pharmaceuticals Corp.'s Reply to Defendant Arriva Pharmaceuticals, Inc.'s Response to Plaintiff's Motion for Protective Order (Jun. 24, 2003)

. 2003 WL 23936899 (Trial Motion, Memorandum and Affidavit) Defendant, Arriva Pharmaceuticals, Inc.'s Response to Plaintiff's Motion for Protective Order (May. 29, 2003)

. 2003 WL 23936891 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion for Protective Order (May. 13, 2003)

. 2003 WL 23936882 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion to Strike Defendant's Last Affirmative Defense and Incorporated Memorandum of

Law (Mar. 19, 2003)

. 2003 WL 23936867 (Trial Motion, Memorandum and Affidavit) Defendant's Motion and Memorandum of Law to Strike Plaintiff's Prayer for Punitive Damages Under Count I (Mar. 03, 2003)

. 2003 WL 23936874 (Trial Pleading) Defendant's Answer and Affirmative Defenses (Mar. 03, 2003)

. 2003 WL 23936856 (Trial Pleading) Complaint for Injunctive Relief and Damages (2003)

END OF DOCUMENT

EXHIBIT E

Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
N.D. Illinois,
Eastern Division.
GLAXO, INC., Glaxo Group Limited, Plaintiffs, Counterdefendants,
v.
TORPHARM, INC., Apotex USA, Inc., Apotex, Inc., Defendants, Counterclaimants.
No. 95 C 4686.

May 18, 1997.

MEMORANDUM OPINION AND ORDER

HART, District Judge.

***1** Glaxo, Inc. and Glaxo Group Limited (collectively, "Glaxo") bring this action against TorPharm Inc., Apotex USA, Inc. and Apotex, Inc. (collectively, "TorPharm"), alleging that TorPharm infringed U.S. Letters Patent 4,521,431 ("the '431 patent") under 35 U.S.C. § 271(e) ("§ 271(e)") by filing an abbreviated new drug application ("ANDA"). Glaxo also seeks a declaratory judgment that the product TorPharm intends to manufacture under the ANDA infringes U.S. Letters Patent No. 4,672,133 ("the '133 patent"). Presently pending is TorPharm's motion for summary judgment.

I. FACTUAL BACKGROUND

Glaxo developed and currently manufactures the well-known anti-ulcer medication, Zantac. The active ingredient in Zantac is the aminoalkyl furan derivative ranitidine hydrochloride ("RHCl"). RHCl is the subject of the '431 patent, the '133 patent and another patent owned by Glaxo, U.S. Patent No. 4,128,658 ("the '658 patent").

RHCl is a salt that occurs in at least two distinct crystalline forms. In 1978, Glaxo was granted the '658 patent, which discloses a method for the production of a form of RHCl known as Form 1 RHCl. The '658 patent expires on July 25, 1997. At the time the patent application was filed, Glaxo did not know that RHCl could occur in more than one crystalline form.

Over the course of the next few years, Glaxo made several batches of RHCl in a pilot plant for further testing and for use in clinical investigations. In 1980, Glaxo scientists produced the thirteenth pilot batch of RHCl. Glaxo determined that this material possessed a different crystalline form than Form 1 RHCl. Glaxo decided that this second crystalline form of RHCl, known as Form 2 RHCl, was preferable to Form 1 RHCl because it possessed better filtering and drying characteristics than Form 1 RHCl. Form 2 RHCl is the active ingredient in Zantac.

Glaxo sought and received two patents covering Form 2 RHCl. The '431 patent, issued in 1985, covers a specific crystalline form or "polymorph" of RHCl. The '431 patent will expire in 2002. The '133 patent covers the processes for making Form 2 RHCl and will expire in 2004. The claims in both the '431 and '133 patents describe Form 2 RHCl by means of a specific, 29- peak infrared spectrum. Claim 2 of the '431 patent further characterizes Form 2 RHCl by a 32-intensity x-ray powder diffraction pattern.

Anticipating the expiration of the '658 patent, TorPharm filed an ANDA with the U.S. Food and Drug Administration ("FDA") on June 5, 1995. TorPharm sought approval to market Form 1 RHCl after the expiration of the '658 patent. As part of its application, TorPharm submitted a "Paragraph IV certification" stating that Glamor's patents will "not be infringed by the manufacture, use or sale of the drug for which the [ANDA] is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Pursuant to 21 U.S.C. § 505(j), TorPharm notified Glaxo of its ANDA filing and the contents of is certifications.

***2** On August 14, 1995, Glaxo sued TorPharm for infringement of the '431 patent under § 271(e). Glaxo believes that TorPharm's product contains Form 2 RHCl in addition to Form 1 RHCl. Glaxo also seeks a declaratory judgment that TorPharm would infringe the '133 patent under 35 U.S.C. § 271(g) by manufacturing and selling the drug for which TorPharm seeks approval. TorPharm moves for summary judgment on both claims on the grounds that Glaxo has no evidence that TorPharm's product infringes any of the claims of the '431 or '133 patents.

II. DISCUSSION

On a motion for summary judgment, the entire record is considered with all reasonable inferences drawn in favor of the nonmovants and all factual disputes resolved in favor of the nonmovants. *Lane Bryant, Inc. v. United States,* 35 F.3d 1570, 1574 (Fed.Cir.1994);

Oxman V. WLS-TV, 846 F.2d 448, 452 (7th Cir.1988); *Jakubiec v. Cities Service Co.,* 844 F.2d 470, 471 (7th Cir.1988). The burden of establishing a lack of any genuine issue of material fact rests on the movant. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.,* 45 F.3d 1550, 1560-61 (Fed.Cir.1995); *Jakubiec,* 844 F.2d at 473. The nonmovant, however, must make a showing sufficient to establish any essential element for which it will bear the burden of proof at trial. *Celotex Corp. v. Catrett,* 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The movant need not provide affidavits or deposition testimony showing the nonexistence of such essential elements. *Id.* at 324. Also, it is not sufficient to show evidence of purportedly disputed facts if those facts are not plausible in light of the entire record. *See Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.,* 984 F.2d 1182, 1191 (Fed.Cir.1993); *Covalt v. Carey Canada, Inc.,* 950 F.2d 481, 485 (7th Cir.1991); *Collins v. Associated Pathologists, Ltd.,* 844 F.2d 473, 476-77 (7th Cir.1988).

Glaxo brings its infringement claim under § 271(e). Section 271(e) is part of the Hatch-Waxman Act, which allows generic drug makers to market generic versions of patented drugs as soon as possible after expiration of the patent. *Glaxo, Inc. v. Novopharm, Ltd.,* 110 F.3d 1562, 1997 WL 156592, *6 (Fed.Cir. April 4, 1997). At the same time, patent holders are provided with limited extensions of patent term in order to recover a portion of the market exclusivity lost during the lengthy process of development and FDA review. *Id.*

Section 271(e)(2) provides that submitting an ANDA is an act of infringement for a drug claimed in a patent or the use of which is claimed in a patent "if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2). The Federal Circuit has held that "the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval." *Novopharm,* 110 F.3d 1562, 1997 WL 156592 at * 6. As in a normal patent infringement case, the burden is on the patent holder to prove by a preponderance of the evidence that what is to be sold infringes. *Id.* "The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Id.* at *8.

*3 Glaxo, however, could not bring a 271(e) claim for infringement of the '133 patent, because 271(e) authorizes only those claims directed to drugs or methods of using drugs. *Id.* at *9. The '133 patent is a process patent, which discloses a method for making a drug, and hence is not covered under § 271(e). Thus, Glaxo has brought a declaratory judgment action seeking a determination that TorPharm's manufacture and sale of RHCl, as potentially approved by the FDA, would infringe the '133 patent.

"A patentee may seek a declaration that a person will infringe a patent in the future," but there must be an actual controversy for a district court to have jurisdiction. *Id.* To demonstrate that an actual controversy exists, a patentee must show that

> "(1) the defendant must be engaged in an activity directed toward ... an infringement charge ... or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming."

Id. at *10 (quoting *Lang v. Pacific Marine and Supply Co.,* 895 F.2d 761, 763 (Fed.Cir.1990)). Since there is no question that TorPharm seeks imminent FDA approval to sell a form of RHCl within the near future, the actual controversy requirement is met and Glaxo's declaratory judgment action will be entertained. *See id.*

An analysis of infringement requires two steps. "The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman V. Westview Instruments, Inc.,* 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The first step, claim construction, is a question of law for the court. *Id.* at 976-79.

The Federal Circuit has already considered the construction of the claims of the '431 and '133 patents in another case brought by Glaxo. *Novopharm. Ltd.,* 1997 WL 156592 at *6. In 1994, Novopharm, Ltd. filed an ANDA seeking approval to market Form 1 RHCl. Similar to this action, Glaxo sued Novopharm for infringement under § 271(e)(2) of the '431 patent and sought a declaratory judgment that the drug for which Novopharm sought approval would infringe the '133 patent. After a bench trial, the district court

entered judgment for Novopharm on all of Glaxo's claims after finding that Glaxo did not prove infringement of its patents. *Glaxo, Inc. v. Novopharm, Ltd.*, 931 F.Supp. 1280, 1286 (E.D.N.C.1996). Glaxo appealed the district court's decision.

Although the Federal Circuit disagreed with the district court's construction of the claims of the '431 and '133 patents, it affirmed the district court's ruling that Glaxo's proof was not sufficient to prove infringement. In reversing the district court's claims construction, the Federal Circuit held that the '431 and '133 patents were not limited to pure Form 2 RHCl, *i.e.*, the claims cover products containing a mixture of Form 2 RHCl and Form 1 RHCl. *Novopharm*, 110 F.3d 1562, 1997 WL 156592 at *3. As to the infringement determination, Glaxo had argued at trial that the district court must analyze infringement based upon a single infrared peak at 1045 cm-. The district court rejected Glaxo's single peak argument and the Federal Circuit agreed, reasoning that "[t]he single peak analysis was ... insufficient because ... in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims." Moreover, the Federal Circuit stated that "Glaxo knew that its decision to claim Form 2 RHCl according to its IR [infrared] and x-ray powder diffraction characteristics would later control the nature of the evidence necessary to prove infringement." *Id.*

*4 Claim 1 of the '431 patent claims "Form 2 ranitidine hydrochloride characterized by an infra-red spectrum as a mull in mineral oil showing the following main peaks...." A table of 29 main peaks in the infrared spectrum are listed. Claim 2, which is dependent on claim 1, claims

> Form 2 ranitidine hydrochloride according to claim 1 further characterized by the following x-ray powder diffraction pattern expressed in terms of "d" spacings and relative intensities and obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoKa radiation and for 2 hours to CuKa radiation.

A table of referenced 32 d-spacings and their relative intensities are listed in claim 2.

TorPharm argues that it is entitled to summary judgment because Glaxo has failed to put forth any evidence that any of the 29 main peaks listed in claim 1 are present in its product's infrared spectrum or that the x-ray diffraction of TorPharm's product contains the 32 d-spacings listed in claim 2 of the '431 patent. As evidence of infringement, Glaxo offers the opinions and tests of Dr. Thomas Niemczyk as to claim 1 and Dr. Peter Stephens as to claim 2. TorPharm, however, contends that their opinions do not constitute admissible evidence of infringement and, as a result, Glaxo has no evidence that TorPharm's product infringes Glaxo's patents.

A. Claim 1--Infrared Spectrum with 29 Main Peaks

To carry its burden as to claim 1 of the '431 patent, Glaxo must submit some evidence showing that the infrared spectrum of TorPharm's product consists of the 29 main peaks listed in claim 1. Glaxo submits the opinion and test results of Dr. Thomas Niemczyk as evidence of infringement. TorPharm argues that Niemczyk's results do not raise a triable issue of fact because Niemczyk compared TorPharm's product against an embodiment of the patent, rather than against the limitations of the claim. Both parties agree that Niemczyk used a reference sample that he created by constructing a statistical model based on his analysis of samples of Form 1 and Form 2 RHCl provided by Glaxo. Niemczyk's reference sample was then compared against TorPharm's product. According to TorPharm, this violates the basic rule that proof of infringement must be based upon a comparison of the accused product against the claims of the patent, not against an embodiment.

The Federal Circuit has consistently held that "it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claim of the patent." *E.g., Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed.Cir.1994); *Martin v. Barber*, 755 F.2d 1564, 1567 (Fed.Cir.1985). In *Zenith*, the claim at issue specified an x-ray diffraction pattern consisting of 37 lines of relative intensities. The reference pattern exhibited by plaintiff's sample consisted of a table of only 30 lines of relative intensities. The Federal Circuit reversed the district court's finding of infringement based upon the improper comparison.

***5** Although Glaxo admits that Niemczyk gathered his reference data from an embodiment, Glaxo contends that the *Zenith's* concerns are not implicated because Niemczyk confirmed that his analysis used all of the 29 main peaks contained in claim 1. Niemczyk's expert report and testimony, however, are confusing as to the role the 29 main peaks played in his analysis. At his deposition, Niemczyk stated that he did not use the table of main peaks in claim 1 and he did not know what was meant by "main peaks," although this phrase

appears in the language of claim 1. In his expert report, Niemczyk stated that he created a calibration model from samples of Form 1 and Form 2 RHCl by implementing a Partial Least Squares ("PLS") algorithm. This model was used to determine that TorPharm's sample contained .5 percent Form 2 RHCl. Niemczyk concluded "[t]he presence of Form 2 in TorPharm's ranitidine hydrochloride necessarily indicates that all of the 29 infrared bands characterizing Form 2 are present." At first glance, it appears that Niemczyk concludes that the 29 main peaks are present only because he already determined through use of a statistical model that TorPharm's product contained Form 2 RHCl. In other words, Niemczyk's methodology did not utilize the 29 main peaks in either analyzing the reference sample or comparing the reference sample to TorPharm's product.

In an affidavit submitted in connection with this motion, however, Niemczyk stated that the PLS calibration model contained the 29 main peaks listed in claim 1 of the patent and that his infrared analysis confirmed the presence of all 29 main peaks in TorPharm's product. TorPharm responds that Niemczyk's affidavit cannot be considered because it contradicts his prior deposition testimony, in which he stated that he did not use the main peak information in claim 1. *See Bank of Illinois v. Allied Signal Safety Restraint Systems,* 75 F.3d 1162, 1168 (7th Cir.1996); *Adelman-Tremblay v. Jewel Cos., Inc.,* 859 F.2d §17, 520-21 (7th Cir.1988) (party cannot create a genuine issue of material fact by submitting an affidavit which contradicts prior deposition testimony).

Because the answer as to whether Niemczyk has used the 29 main peaks as a basis for identifying Form 2 RHCl in TorPharm's product is essentially a judgment as to the credibility of Glaxo's expert, it would not be proper to decide this question on a motion for summary judgment. Inconsistencies in Niemczyk's testimony will be resolved in favor of Glaxo. Construing the evidence in the light most favorable to Glaxo, Niemczyk's affidavit could be seen as a further explanation of his methodology, rather than a direct contradiction. Thus, Niemczyk's opinion and test results will not be disregarded on this basis.

Second, TorPharm argues that claim 1 defines a basic methodology that Glaxo must follow to prove infringement: Glaxo must show all 29 main peaks can be visually identified in a mull in mineral oil. TorPharm contends that Niemczyk impermissibly "employed a complex, computerized method of mathematical calculation, consisting of various statistical principles, to 'predict' " the existence of Form 2 RHCl in TorPharm's product. TorPharm asserts that Niemczyk's opinion and results should not be considered because Niemczyk failed to follow the limitation in claim 1 that all 29 main peaks must be visually identified in a mull in mineral oil.

***6** Glaxo acknowledges that Niemczyk has not attempted to empirically identify, *i.e.,* through direct visual observation, whether TorPharm's product contains the 29 main peaks listed in claim 1. Niemczyk testified, however, that he has determined that all 29 main peaks are present in TorPharm's product as a result of a PLS infrared spectral analysis. Glaxo contends that it is not limited to conventional, visual analysis of spectral data to prove infringement. Glaxo argues that visual analysis is inaccurate where, as here, the unknown sample is a mixture of compounds. Niemczyk testified that an unknown compound can be identified by visually comparing the infrared spectrum of the unknown sample with the infrared spectra of known compounds. Niemczyk further testified that when an infrared spectral analysis is performed on a mixture of chemical compounds, as opposed to an isolated chemical compound, the spectrum of the mixture of compounds will be different from the individual spectrum for each compound. Niemczyk stated that analysis by a visual comparison of the infrared spectrum of the mixture with the spectra of known compounds is difficult and imprecise.

Niemczyk sets forth the alternate testing procedure he used with the sample of TorPharm's product in his expert report. After obtaining the spectral data from TorPharm's sample, Niemczyk used a multivariate calibration method, Partial Least Squares, to determine that infringement existed. A Partial Least Squares or PLS calibration correlates the changes in the spectra obtained from calibration sample with the known property, in this case Form 2 RHCl. Dr. Niemczyk concluded from his PLS analysis that the sample of TorPharm's product that he tested contained approximately .5 percent Form 2 RHCl.

The question of permissible methodology is complicated because the Federal Circuit has definitively held that the '431 patent covers a mixture of Form 1 and Form 2 RHCl and that the infrared characteristics defined in the claim "controls" the method of proof. *Novopharm,* 110 F.3d 1562, 1997 WL 156592 at *3. Yet if Glaxo is right that conventional infrared analysis is inaccurate on a mixture of Form 1 and Form 2 RHCl--and no opinion is expressed as to whether it is--then Glaxo is left with

the problem of how to prove that a mixture of Form 1 and Form 2 RHCl infringes its patents.

Glaxo's argument in favor of its methodology boils down to a contention that Niemczyk used the technique described in claim 1 to obtain the spectrum data on TorPharm's sample and he used PLS only to *interpret* the data. This inference is not unreasonable in light of the submitted testimony of Niemczyk. Claim 1 does not specifically state that identification of the main peaks must be visual; it only states that Form 2 RHCl is characterized by a mull in mineral oil "showing" the 29 main peaks. If reading the infrared results visually is inconclusive, Glaxo may be able to satisfy its burden of proof by presenting a more accurate method interpretation of the infrared spectrum of TorPharm's product to demonstrate infringement. According to Niemczyk, this method is advantageous because it separately analyzes the infrared spectrum of each component in the mixture. In addition, on a motion for summary judgment, the factual question of the accuracy of Niemczyk's interpretation of the infrared spectrum of TorPharm's product will be resolved in Glaxo's favor. Thus, to the extent that Niemczyk's analysis merely interprets the infrared spectrum of TorPharm's product rather than deviates from a method of proof which demonstrates infringement by showing the presence of the 29 main peaks in the infrared spectrum of TorPharm's' product, Glaxo's evidence will not be rejected on a motion for summary judgment.

***7** TorPharm offers a final reason for granting summary judgment in its favor in its reply memorandum to Glaxo's opposition memorandum. TorPharm asserts that its specification in its ANDA requires a polymorphic purity of 99.37%. TorPharm asserts that this level of purity demonstrates non-infringement because the Federal Circuit affirmed *Novopharm* even though Glaxo brought forth evidence that Novopharm's polymorphic purity specification would permit it to market a Form 1 RHCl product with a polymorphic purity as low as 90 percent. Glaxo itself asserts that TorPharm's product contains only .5 percent Form 2 RHCl. In *Novopharm,* however, the Federal Circuit expressly noted that "[t]he district court did not decide whether small amounts of Form 2 RHCl in a mixture with Form 1 RHCl would infringe the '431 patent." *Novopharm,* 110 F.3d 1562, 1997 WL 156592 at *13 n. 1. In any event, TorPharm has raised the issue in its reply memorandum, rather that its motion, and has offered no other authority supporting its position. Thus, the issue of whether a *de minimis* amount of Form 2 RHCl infringes the '431 patent is reserved for further consideration.

Niemczyk's testimony sufficiently creates a triable issue of fact as to infringement of claim 1 of the '431 patent. Summary judgment will be denied as to claim 1 of Glaxo's claim for infringement of the '431 patent. Because Glaxo has presented some evidence of infringement by TorPharm's product, summary judgment will also be denied as to Glaxo's declaratory judgment action.

B. Claim 2--32 D-Spacings in X-Ray Diffraction Pattern

TorPharm asserts that Glaxo has failed to present any admissible evidence of infringement of claim 2 of the '431 patent because, similar to its argument as to claim 1, its expert did not use the methodology specified in the claim. Claim 2, unlike claim 1, expressly identifies the method by which x-ray diffraction pattern must be demonstrated--the claim states that the pattern must be "obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoKa radiation and for 2 hours to CuKa radiation." Glaxo's decision to claim Form 2 RHCl according to this methodology controls. See *Novopharm,* 110 F.3d 1562, 1997 WL 156592 at *4. Glaxo must use this methodology to demonstrate infringement.

Glaxo's expert, Dr. Stephens, did not use the Debye Scherrer method to obtain the x-ray diffraction results Glaxo submits in connection with this motion. Instead, he used the capabilities of the National Synchrotron Light Source at Brookhaven National Laboratory. Dr. Stephens stated in his expert report that "[s]ychrotron radiation sources are generally more intense than laboratory sources." Using the National Synchrotron Light Source, Stephens reports that he identified four of the 32 d-spacings listed in claim 2. Stephens states in his affidavit that on the basis of those matching peaks and his indexing of Form 1 and Form 2 RHCl, it is a "scientific certainty" that TorPharm's product contains Form 2 RHCl. Stephens concludes that "it follows from the presence of Form 2 in [TorPharm's sample] and the results of my indexing of Form 2 that all diffraction peaks at all of the allowed positions of the Form 2 pattern are present ... this demonstrates that all 32 diffraction peaks *i.e.,* d-spacings listed in claim of the '431 patent are present." Stephens notes, however, that he could have detected that TorPharm's sample contained Form 2 RHCl by using "x-ray film techniques, such as those described in claim 2."

***8** Glaxo has not offered any evidence that demonstrates that TorPharm's product meets all of the

claim limitations of claim 2. As an initial matter, Glaxo would be required to use the method prescribed in the patent, the Debye Scherrer method, to prove infringement. Even assuming that Stephens's statement that he could have used the Debye Scherrer method to detect Form 2 RHCl in TorPharm's sample would be acceptable for purposes of surviving summary judgment, Stephens did not find 28 of the 32 d-spacings in the x-ray diffraction pattern of TorPharm's sample. Stephens's circular reasoning--four d-spacings exist, therefore the product must be Form 2, therefore all 32 d-spacings are present--is identical to the single peak theory rejected by the Federal Circuit. Glaxo was required to bring forth evidence that TorPharm's product would exhibit an x-ray diffraction pattern with the 32 listed d-spacings using the Debye Scherrer method. Glaxo has failed to do so. Summary judgment will be granted in TorPharm's favor as to claim 2 of the '431 patents.

IT IS THEREFORE ORDERED that:

(1) The motion for summary judgment of defendants TorPharm, Inc., Apotex USA, Inc. and Apotex, Inc. [120-1] is granted in part and denied in part. Summary judgment is granted as to claim 2 of the '431 patent. Summary judgment is denied as to claim 1 of the '431 patent and as to Glaxo's declaratory judgment action.

(2) TorPharm is directed to file, within 10 days, a brief not to exceed 10 pages and supporting materials, if any, on the issue of whether a .5 amount of Form 2 RHCl in a mixture with Form 1 RHCl, would infringe claim 1 of the '431 patent. Glaxo may file a brief not to exceed 10 pages and supporting materials, if any, within 10 days thereafter. TorPharm may file a 5-page reply brief within 10 days thereafter.

(3) The stay entered in this case is vacated.

Not Reported in F.Supp., 1997 WL 282742 (N.D.Ill.)

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